UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,053	01/29/2002	Robert M. Jones	2314-248	3665

6449 7590 07/16/2003

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER
WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
1637	9

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,053	JONES ET AL.	
	Examin r	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to an isolated peptide, classified in class 530, subclass 300.

II. Claims 17-19, drawn to an isolated nucleic acid, classified in class 536, subclass 23.1.

III. Claims 20-48, drawn to a method for treating with drug, classified in class 514, subclass 12.

IV. Claims 49-53, drawn to a method for identifying a drug, classified in class 435, subclass 7.1 .

V. Claims 54-56, drawn to a method for characterizing a new site on an ion channel classified in class 435, subclass 7.92.

VI. Claim 58, drawn to a method for designing a β-beta turn, classified in class 424, subclass 1.11.

VII. Claims 58-61, drawn to a method of identifying a ligand that binds to a G-protein coupled receptor, classified in class 435, subclass 7.1.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Applicant must further elect a single SEQ ID

NO. Applicant must specifically identify each of the corresponding SEQ ID NO: X, SEQ ID NO: Y for the sequence elected along with the corresponding elected claims.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. The sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence or amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 eq seq. By statute, "[i}f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the invention". "35 U.S.C. 121." Pursuant to this statute, the rules provided that "[i]f two or more independent and distinct invention are claimed in a single application, the examiner in his action shall require the Applicant....to elect that invention to which his claim shall be restricted". 37 CFR 1.142(a). See also 37 CFR 1.141(a).

Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election. Non-elected sequences in multiple sequence claims will be withdrawn from prosecution.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of I and II are distinct in structure and physicochemical properties. Inventions I is drawn to an isolated peptide whereas invention II is drawn to an isolated nucleic acid. Because peptides are composed of amino acids and the isolated nucleic acid composed of nucleotides, the inventions have different structural and functional properties as well. Furthermore, the different inventions of I and II can be utilized in different methodologies, such that the peptide is used in e.g., ligand binding assays whereas the nucleic acid is utilized in e g., hybridization and amplification assays. The nucleic acid of invention II is not required to

produce the peptide of invention I because the peptide can be isolated directly from nature or chemically synthesized.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the invention of Group I, namely the peptide, can be used in a materially different process besides in treatment methodologies. The peptide can be used in immunoassays or immunoprecipitation assays or in Western blotting techniques to determine expression of a ligand of interest.

Inventions I and IV, V, VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the invention of Group I, namely, the polypeptide can be used in a materially different process besides those recited in Groups IV, V and VII. The peptide can be used in immunoassays or immunoprecipitation assays or two hybrid systems.

4. Inventions I and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the peptide can be designed by a materially different process besides that of invention VI. For

example, the peptide of invention I can be enzymatically synthesized using molecular techniques.

5. Inventions II and III, IV, V, VI, VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the different invention have different modes of operations leading to different effects. For example, invention is drawn to an isolated nucleic acid which can be utilized in nucleic acid hybridization and amplification assays whereas, invention III is drawn to treatment methods using a compound or drug administered to an individual to alleviate or mimic the condition being treated. The invention IV differs from the other inventions in that the invention of Group IV is drawn to a screening method for identifying a drug candidate via a ligand and/or receptor binding assays. The method of invention V differs from the other inventions in that it is drawn to a peptide binding assay for characterizing a new site on a voltage gated ion channel or ligand-gated ion channel and receptor. The method of invention V utilizes parameters of fluorescence, phosphorescence and illuminescence to measure binding. The method of invention VI differs from the other inventions in that it is drawn to a method for designing a β-beta turn that mimetic of a beta-superfamily conotoxin via chemical synthesis processes and the method of invention VII differs from the other inventions in that it is drawn to a method of identifying a ligand that binds to a receptor via a binding assay which utilized a radiolabeled derivative of that allows measurement of the interaction between the peptide and G-protein coupled receptor. The different inventions require different starting materials, method steps and further are patentably distinct because they require different fields of search.

6. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

Cynthia B. Wilder, Ph.D.
Examiner
Art Unit 1637

cbw
July 13, 2003